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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,119	02/21/2002	Christoph Reinhard	PP-16932.002	8543

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,119	REINHARD ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 5* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: claim 1 has been amended to recite the subject matter of claim 3, "TTK antisense polynucleotides". This phrase is unclear because TTK is not defined until line 4 of the claim. It is suggested that for the sake of clarity the claim be rewritten to include the full name of TTK at its first appearance in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is indefinite because it depends from claim 3, which has been cancelled.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of record of claims 1, 2, 4, 5 and 7 under 35 USC 112, first paragraph for failing to comply with the enablement requirement is withdrawn in view of the amendment made January 26, 2005.

The rejection of record of claim 7 under 35 USC 112, first paragraph for failing to comply with the written description requirement is withdrawn in view of applicants arguments of January 26, 2005.

Claims 1, 2, 4 and 5 are maintained as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 is drawn to a method of reducing the growth of a cancerous cell *in vitro* by contacting the cell with a TTK antisense polynucleotide that is effective in reducing tyrosine threonine kinase (hereafter referred to as TTK) polypeptide activity. Claim 2 limits claim 1 by stating the reduction of TTK activity is a result of reduced TTK polypeptide levels. Claim 4 limits claim 3 by stating the antisense polynucleotide is contained within a viral-based vector. Claim 5 limits claim 1 by stating the reduction of TTK activity is a result of a reduction of TTK polynucleotide levels.

1. Claim 1 encompasses the use of antisense polynucleotides that reduce TTK polypeptide activity. The specification teaches at page 8 the scope of TTK polypeptides that are targeted in the instant invention. TTK polypeptides are defined as

encompassing not only human TTK, but also genes from two species of yeast, "other genes and gene products related to TTK" and polypeptides having as little as 65% sequence similarity or sequence identity. The genus of possible targets encompassed by the scope of the definition of TTK polypeptides provided in the specification is large and includes genes or gene products that may coincidentally share 65% sequence identity with TTK but have no function related to the kinase activity of TTK. The sequences of the TTK antisense polynucleotides disclosed on page 31 as reducing TTK activity are not representative of the full breadth of the genus encompassed by the scope of the claims. The disclosed antisense polynucleotides do not share a common structure that has been shown in the instant application or is known in the art to impart the function of reducing TTK activity by targeting yeast genes, genes related to TTK or genes that coincidentally share a degree of sequence identity but have an unrelated function. The antisense sequences provided do not serve to describe embodiments of the genus of antisense that are directed to related genes that are encompassed by the instant claims.

2. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

3. MPEP 2163 states in part, "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical

name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")."

4. With the exception of the antisense sequences targeted to human TTK disclosed on page 31 of the specification, the skilled artisan cannot envision the detailed structure of the encompassed antisense sequences that reduce TTK polypeptide activity. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

5. Therefore, the claimed methods do not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath

makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments

6. Applicant's arguments filed January 26, 2005 have been fully considered but they are not persuasive. Applicants have amended claim 1 to narrow the scope of the agent used in the method to antisense polynucleotides. Applicants assert that the claims as amended possess adequate written description and cite example 15 of the written description training materials provided to examiners beginning in January 2001 as evidence, stating that the scenario is "almost identical" to the instant application. This argument is not persuasive because there are actually significant differences between the instant application and the cited example. First, the claim from the example is directed to a compound, while the instant claims are method claims. Second, the cited example has a narrow scope, claiming antisense sequences complementary to a single gene sequence, the sequence of which is recited in the claim. The instant application, however, is claiming use of antisense polynucleotides to reduce activity not of a particular sequence, but of a "TTK polypeptide". As discussed in the body of the rejection, the encompassed genes, gene products and species having sequence identity or sequence similarity to the genes that are defined in the specification as being TTK polypeptides constitute a broad genus that is not described by the instant application.

Allowable Subject Matter

Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

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SEAN McGARRY
PRIMARY EXAMINER

Tracy Vivlemore
Examiner
Art Unit 1635

TV
March 29, 2005

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PRIMARY EXAMINER
1635